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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,008	01/03/2006	Sanjay Suri	05-40052-US	8800
7590		12/19/2007		
Louis M Heidelbergger Reed Smith 2500 One Liberty Place 1650 Market Street Philadelphia, PA 19103				
			EXAMINER	
			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			12/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Office Action Summary</b></p>	<p>Application No.</p> <p align="center">10/529,008</p>	<p>Applicant(s)</p> <p align="center">SURI ET AL.</p>	
	<p>Examiner</p> <p align="center">Rita J. Desai</p>	<p>Art Unit</p> <p align="center">1625</p>	<p></p>

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1-15 are pending.

The objection to claim 15 has been withdrawn as applicant have put in the dependency from claim 1.

The rejection of claims 1-15 under 35 USC 103 over following references independently.

- 1)WO -A -9510514, 1995, Bhisop Robert et al
- 2)Chemical and Pharmaceutical Bulletin, JP (11-1999), 42(11) 2285-2290. Iwasaki et al
- 3)Tetrahedron 1998... Sejas et al
- 4)WO -A- 9631478,1996, Afonso et al.
- 5)EP 0,208,855 cited in application page 3.
- 6)EPO,152,897 cited in application page 3.
- 7)US, 4,659,716 cited in application page 3.
- 8)Hu 194,864 cited in application page 2.

In dependently and also ,All in view of Peon Jorge et al 2001

Applicants arguments are not convincing. Applicant argue

In order to establish *prima facie* case of unpatentability in chemical cases, a showing that the "prior art would have suggested making the specific modifications necessary to achieve the claimed invention" is also required. *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995). While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness analysis, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the element, in the way the claimed new invention does" in an obviousness determination. *KSR*, 127 S. Ct. at 1731. Further, the Court indicated that there is "no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *Id.* As long as the test is not applied as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry.

*Id.* Thus, in chemical cases, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.

Applicants further argue that the examiner has not made a *prima facie* case , this is incorrect.

The need to make a better process is there as the compounds are of commercial value.

Making it faster would make the process more efficient and hence cheaper in the long run.

Using neat alcohol instead of aqueous make the fuel cell more efficient and faster according to Peon Jorge et al.

Us 4659716 in column 4 , lines 38-39 teaches using a neat t-butyl alcohol, in the process of preparing Loratadine.

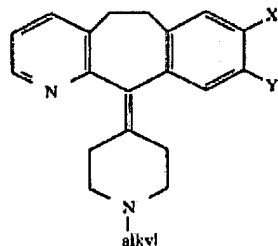
Applicants process is to prepare DCI but from loratadiene.

4,659,716

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ying a noble  
or platinum  
methyl pyri-

5



III



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such KOH,  
acid of for-

15

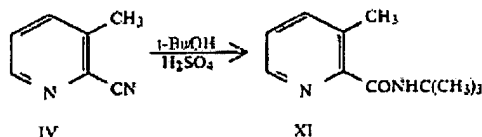
The compound of formula IX may also be reacted with Na in liquid  $\text{NH}_3$  and a 4-halo-N-alkyl-piperidine to produce the compound of formula X.

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In an alternative method 2-cyano-3-methylpyridine can be reacted in a Ritter reaction with a tertiary butyl compound in an acid such as concentrated sulfuric acid or concentrated sulfuric acid in glacial acetic acid to form a compound of formula XI



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IV

XI

yclized, e.g.,  
loride, to a

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Suitable tertiary butyl compounds include, but are not limited to, t-butyl alcohol, t-butyl chloride, t-butyl bromide, t-butyl iodide, isobutylene or any other compound which under hydrolytic conditions forms t-butyl carboxamides with cyano compounds. The temperature of the reaction will vary depending on the reactants, but generally the reaction is conducted in the range of from about  $50^\circ\text{C}$ . to about  $100^\circ\text{C}$ . with t-butyl alcohol. The reaction may be performed with inert solvents but is usually run neat.

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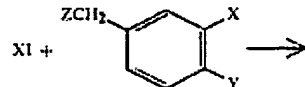


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The product of the Ritter reaction (formula XI) can be reacted with an appropriate 3 and/or 4-halo or trifluoromethyl-substituted benzyl halide, in the presence of a base to form the compound of formula XII

ard reagent  
to produce

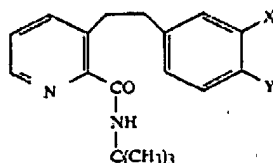
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XII

such as poly-  
compound of

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wherein Z is chloro, bromo or iodo. Examples of appropriate benzyl halides include, but are not limited to, 3-chloro-benzyl chloride, 3-fluoro-benzyl bromide, 3,4-dichloro-benzyl chloride, 4-fluoro-benzyl chloride, 3-trifluoromethyl-benzyl chloride, 3-bromobenzyl chloride, etc. Any suitable base can be employed e.g., an alkyl lithium compound such as n-butyl lithium in tetrahydrofuran (THF). Preferably the base has a  $\text{pK}_a$  of greater than 20 and more preferably greater than 30.

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In this case too the carbonium ion is is formed.

The Jorge reference just explains the mechanism with the neat alcohol.

US 5595957 as disclosed in the specifications also uses absolute ethanol, which is same as neat alcohol.

Changing solvents and modification of reaction conditions is prima-facie obvious to one of skill in the art to come up with a process which gives a higher yield, or is purer or has a better coloration.

Crystallization is also a routine process of purification of compounds.

Applicants modifications are so routine that the examiner is having a hard time articulating what is well known in the art.

Practical Methods of Organic Synthesis by Ludwig Gutterman, clearly teaches crystallization as a process of purification.

ions are, only in rare cases, pure, they must therefore be subjected to a process of purification before they can be further utilised. For this purpose the operations most frequently employed are :

1. CRYSTALLISATION.
2. SUBLIMATION.
3. DISTILLATION.

#### CRYSTALLISATION

**Methods of Crystallisation.** — The crude product obtained directly as the result of a reaction is, in case it is a solid, generally amorphous or not well crystallised. In order to obtain the compound in uniform, well-defined crystals, as well as to separate it from impurities like filter-fibres, inorganic substances, by-products, etc., it is dissolved, usually with the aid of heat, in a proper solvent, filtered from the impurities remaining undissolved, and allowed to cool gradually. The dissolved compound then separates out in a crystallised form, while the dissolved impurities are retained by the mother-liquor. (*Crystallisation by Cooling.*) Many compounds are so easily soluble in all solvents, even at the

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I

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#### GENERAL PART

ordinary temperature, that they do not separate from their solutions on mere cooling. In this case, in order to obtain crystals, a portion of the solvent must be allowed to evaporate. (*Crystallisation by Evaporation.*)

**Solvents.** — As solvents for organic compounds, the following substances are principally used :

- CLASS I. Water,  
Alcohol,  
Ether,  
Ligroin (Petroleum Ether),  
Glacial Acetic Acid,  
Benzene.

The rejection still stands. Applicants have not provided any comparison or unexpected results as to why applicants process is an improved one.

*Conclusion*

Claims 1-15 still stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
December 7, 2007

*RJ Desai*  
12/7/07